UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ERIK MIDDELMAN and VAN ELEONOOR ANDEL

Appeal 2007-0861
Application 09/381,484
Technology Center 1700

Decided: September 25, 2007

Before ERIC GRIMES, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of improving weight gain in preterm infants. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

"The long chain polyunsaturated fatty acids (LC PUFA) have been shown to be important in infant development. Particularly, arachidonic acid (ARA) and docosahexaenoic acid (DHA) are LC PUFA that are of special

interest in infant nutrition because they are found in high concentrations in the brain . . . and the retina." (Specification 1: 9-15.)

The Specification states that several

> prior art studies have documented the value of administering DHA to infants. However, when DHA, either as the primary LC PUFA or combined with EPA, is administered to preterm infants, said infants suffer from decreased growth. It has been suggested that ARA may be beneficial to growth; however, heretofore the growth effects of administering both DHA and ARA to preterm infants have been unknown.

(*Id.* at 4: 8-13.)

The Specification discloses that "preterm infants receiving infant formula supplemented with both DHA and ARA demonstrate enhanced growth. The present invention is directed to enhancing the growth of preterm infants comprising administering to said infants a growth enhancing amount of DHA and ARA." (*Id.* at 3: 27 to 4: 1.)

DISCUSSION

1. CLAIMS

Claims 1-5 and 21 are pending and on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 1, the broadest claim on appeal, which reads as follows:

> Claim 1. A method for enhancing the weight gain of preterm infants comprising administering to said infants a weight gain enhancing amount of DHA and ARA, wherein the weight gain enhancing amount comprises DHA in an amount of at least about 10 mg/100 kcal and ARA in an amount of at least about 30 mg/100 kcal, wherein the DHA and ARA are added into nutritional products or nutritional supplements for preterm infants.

2. PRIOR ART

The Examiner relies on the following references:

Kyle	US 5,374,657	Dec. 20, 1994
Schweikhardt	EP 0,231,904	Aug 12, 1987

Crozier, "Metabolism of long chain polyunsaturated fatty acids and infant nutrition," Monatsschrift Fur Kinderheilkunde, Vol. 143, No. 7 (suppl. 2), pp. S95-S98 (1995)

3. OBVIOUSNESS

Claims 1-5 and 21 stand rejected under 35 U.S.C. § 103 as obvious in view of Kyle, Crozier, and Schweikhardt. The Examiner finds that Kyle teaches infant formula containing DHA and ARA in amounts comparable to those in human breast milk, which the Examiner has calculated to be 26 mg/100 kcal of ARA and 8 mg/100 kcal of DHA (Answer 3[1]). The Examiner notes that Kyle does not teach feeding the supplemented formula to preterm infants but cites Crozier and Schweikhardt as suggesting this aspect of claim 1.

The Examiner cites Crozier's disclosure that ARA and DHA are important for proper growth and development of preterm infants (Answer 4) and Schweikhardt's disclosure of infant formula, for feeding to preterm infants, that contains ARA and DHA in amounts the Examiner calculates to

[1] In the Answer, the Examiner actually states the units as "mg/kcal" rather than mg/100 kcal. However, the Examiner cites the amendment filed by Appellants on Nov. 17, 2003 to support his calculations; that paper states the same numbers with units of "mg/100 kcal."

be 5-42 mg/100 kcal of ARA[2] and 1.7-17 mg/100 kcal of DHA (*id.*).[3] The Examiner concludes that a

> person of ordinary skill in the art would have been motivated to make a infant formula with the particular amount of ARA and DHA herein and use the same for feeding pretermed infant, because preterm infants are known to be in need of food with sufficient amount of ARA and DHA and the particular amounts of ARA and DHA herein are overlapped with the amounts range known in the art. The particular amount herein is considered obvious variation within the known range.

(*Id.* at 4-5.)

We agree with the Examiner that the cited references support a prima facie case of obviousness. Kyle teaches that "ARA and docosahexaneoic acid (DHA) are critical elements of muscle, organ and vascular tissues" (Kyle, col. 1, ll. 26-28). Kyle discloses an infant formula supplemented with "a blend of DHA single cell oil and ARA single cell oil" to provide "ARA and DHA levels equivalent to human breast milk" (*id.* at col. 13, ll. 25-55). Kyle does not specifically teach feeding the disclosed infant formula to preterm infants.

Crozier states that

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[2] Again, the Answer states the units in "mg/kcal" rather than mg/100 kcal but since the Examiner bases his calculations on the amount of infant formula required to provide 100 kcal of energy (Answer 4), it is apparent that "mg/100 kcal" was intended. Appellants' calculations (see fn. 3) are consistent with this understanding.

[3] Appellants calculate the amounts to be 6.3-52.9 mg/100 kcal ARA and 2.6-26.5 mg/100 kcal DHA. (Br. 7: 1-3; 10: 13-15.) We need not resolve whose calculations are correct, however, since both calculated ranges overlap with the ranges recited in claim 1.

> [t]here is increasing evidence that the premature infant may require a dietary source of preformed 20 and 22 carbon long chain polyunsaturated fatty acids (LCPUFA). These LCPUFA, especially arachidonic acid (AA, 20 : 4 n-6) and docosahexaenoic acid (DHA, 22:6 n-3), are necessary for proper growth and development and are consistently found in human milk.

(Crozier, p. S96: Summary.)

Schweikhardt teaches that the "newborn baby, particularly the premature baby, is . . . dependent on the exogenous supply of highly unsaturated polyethenoid fatty acids such as e.g. arachidonic and docosahexaenoic acids" (Schweikhardt, p. 1, ¶ 3).[4] Schweikhardt discloses a "fat mixture for infant feeds" containing ARA and DHA "in a ratio of docosahexaenoic to arachidonic acid of 1:2.0 to 1:3.0, wherein the content of arachidonic acid in the fat mixture is 0.12 to 1.0 wt.% and that of docosahexaenoic acid 0.05 to 0.5 wt %" (*id.* at p. 2, ¶ 4).

The Examiner has calculated that the wt.% ranges recited in Schweikhardt correspond to 5-42 mg/100 kcal of ARA and 1.7-17 mg/100 kcal of DHA, while Appellants have calculated the ranges to correspond to 6.3-52.9 mg/100 kcal ARA and 2.6-26.5 mg/100 kcal DHA. The Examiner and Appellants therefore agree that Schweikhardt discloses ranges of ARA and DHA that overlap those recited in claim 1. Schweikhardt teaches that the disclosed "fat mixture . . . is suitable for the preparation of infant and premature baby feed" (*id.* at p. 5, ¶ 1).

We agree with the Examiner that those of ordinary skill in the art would have considered it obvious, in view of the cited references, to

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[4] Our citations to Schweikhardt refer to the English-language translation.

administer to preterm infants an infant formula containing at least 10 mg/100 kcal of DHA and 30 mg/100 kcal of DHA. The method defined by instant claim 1 is therefore unpatentable under 35 U.S.C. § 103.

Appellants argue that "the combination of Kyle, Crozier and Schweikhardt does not teach or suggest a method of *enhancing the weight gain* of preterm infants by administering to the infant a weight gain enhancing amount of DHA and ARA" (Br. 8). In response to the Examiner's argument that enhanced weight gain is simply another advantage of an otherwise obvious process (Answer 6), Appellants argue that the inherency cases cited by the Examiner apply only to products, not processes (Br. 17-18) and that, in any case, "an inherency argument should not be maintained in connection with an obviousness rejection" (*id.* at 18).

We do not find any of these arguments persuasive. First, we agree with the Examiner that the "weight gain enhancing" recitations in claim 1 should be given no patentable weight. The preamble of claim 1 recites a "method for enhancing the weight gain of preterm infants." A preamble can sometimes constitute a claim limitation. *See, e.g., Pitney Bowes Inc. v. Hewlett Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). For example, the preamble of a claim to a therapeutic method can limit the patients on whom the method is to be practiced. In this case, the preamble states that the method is for "preterm infants" and provides antecedent basis for the "said infants" recited in the body of the claim. Therefore, the preamble effectively requires that the claimed method be performed on preterm infants.

However, the recitation of a "method for enhancing the weight gain" in claim 1's preamble does not further limit the claim and therefore does not constitute a claim limitation. *Cf. Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 246 F.3d 1368, 1371 (Fed. Cir. 2001): Preamble language stating that a claimed method was "for reducing hematologic toxicity" was held not to further limit the claim. "The steps of the . . . method are performed in the same way regardless whether or not the patient experiences a reduction in hematologic toxicity, and the language of the claim itself strongly suggests the independence of the preamble from the body of the claim."

Similarly here, whether ARA and DHA are added to preterm infant formula in the recited amounts for the purpose of enhancing weight gain or for some other purpose changes nothing about how the steps recited in claim 1 are performed. Thus, the "enhancing weight gain" recitation in the preamble is not a claim limitation. Likewise, the recitation of "a weight gain enhancing amount of DHA and ARA" in the body of claim 1 adds nothing to the specific amounts of DHA and ARA that are also recited in the claim.

Appellants' argument that inherency does not apply to process claims is contrary to case law. *See In re Woodruff*, 919 F. 2d 1575, 1578 (Fed. Cir. 1990) ("It is a general rule that merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable."); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005) ("[W]hen considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure.").

Finally, we also disagree with Appellants' argument that inherency has no place in an obviousness analysis. It is true that an unknown, inherent property cannot be relied on as a reason for combining the teachings of the prior art. *See In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) ("'That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.' Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.").

However, it is also true that the prior art need not suggest combining references for the same reason that a patent applicant combined them. *See KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741-42 (2007) ("In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. . . . [A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.").

Here, the cited references would have suggested feeding preterm infants a formula containing ARA and DHA because they are "critical elements of muscle, organ and vascular tissues" (Kyle, col. 1, ll. 26-28), because they "are necessary for proper growth and development" (Crozier, p. S96, Summary), and because "it is known that the growing organism needs large quantities of these substances (cholesterol, arachidonic acid, docosahexaenoic acid) in a certain ratio to each other for the synthesis of new cell wall material" (Schweikhardt, p. 1, ¶ 2). The cited references therefore would have made obvious the method defined by claim 1.

Appellants argue, however, that the prior art taught that adding DHA alone to infant formula resulted in a slowing of weight gain compared to unsupplemented formula (Br. 3, last paragraph). Appellants argue that "Crozier teaches away from the present invention" because it "cites a study in which DHA from fish oil was administered to preterm infants and the 'growth' and 'weight gain' of the infants was '*significantly depressed.*'" (*Id.* at 11.) Appellants argue that "[w]hile Crozier does suggest supplementing DHA and ARA into the diets of preterm infants, it is . . . *not* for the purpose of enhancing weight gain" (*id.* at 12).

We do not find this argument persuasive. First, for the reasons discussed above, Crozier's reasons for suggesting the claimed method are irrelevant to whether the method would have been obvious.

Second, we do not agree that Crozier teaches away from the claimed method. Crozier does indeed discuss "[e]arly experiments [that] looked at formula supplemented with fish oil since fish oil contained preformed DHA" (Crozier, p. S96, Summary). Crozier reports that in those experiments "growth was significantly depressed" (*id.*). Crozier does not, however, attribute this effect to the DHA in the formula; it states that the effect "may be due to the presence in fish oil of eicosapentaenoic acid (EPA, 20 : 5 n-3) which has structural similarities to" ARA. Crozier recommends as a source of DHA "[c]ertain fish oils [that] are low in EPA" as "acceptable ingredients in infant formula" (*id.* at S98, middle column).

Thus, a person of skill in the art would understand Crozier to teach that the slowed weight gain found in previous experiments was a result of using a source of DHA that also contained EPA, rather than a result of the

DHA itself. Therefore, we do not agree that Crozier would have taught away from the claimed method.

Appellants also argue that the Specification provides evidence of unexpected results. Specifically, Appellants assert that there was a "general consensus among those of ordinary skill in the art" that DHA lowers weight gain among preterm infants. (Br. 12-13, citing Crozier and two other research papers). Appellants argue that, based on this expectation, "*any* increase in weight gain due to DHA and ARA supplementation would be unexpected. . . . Applicant not only states that the results obtained in the present invention were surprising and unexpected, based on the knowledge within the art (page 4, lines 7-21), but also supports that expectation with specific data demonstrating the improved results" (*id.* at 13-14).

We do not agree that Appellants' evidence overcomes the prima facie case of obviousness. First, we disagree with Appellants' position that those skilled in the art would have expected DHA-supplemented infant formula to cause slower growth compared to unsupplemented formula. Crozier states that the effect seen in the prior experiments was likely due to the presence of eicosapentaenoic acid in the fish oil that was used as a source of DHA (Crozier, page S96, Summary) and recommends using other fish oils that are low in that fatty acid (*id.* at S98, middle column). The two other studies cited in the Brief are not of record. Thus, the evidence of record does not support Appellants' position that those skilled in the art would have expected DHA supplementation to slow infant growth.

In addition, Appellants have not compared the claimed method to the closest prior art. The closest prior art in this case is provided by Kyle, not Crozier, as argued by Appellants (Br. 17). Kyle discloses infant formula containing ARA and DHA in amounts "equivalent to human breast milk," which the Examiner has stated (and Appellants have not disputed) are 26 mg/100 kcal ARA and 8 mg/100 kcal DHA. Kyle differs from claim 1 in only two ways: (1) the amounts of ARA and DHA are slightly lower than the levels recited in instant claim 1, and (2) Kyle does not disclose feeding the disclosed formula to preterm infants.

Thus, the appropriate comparison for showing unexpected results would be Kyle's formula fed to full-term infants compared to the formula recited in claim 1 fed to preterm infants. The results of such a comparison are not of record, and thus Appellants have not shown that the claimed method provides unexpectedly superior results compared to the closest prior art.

SUMMARY

The cited references support a prima facie case of obviousness with respect to claim 1, which Appellants have not rebutted. We therefore affirm the rejection of claim 1. Claims 2-5 and 21 fall with claim 1.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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